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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/367,748 11/19/99 DIEMBECK W BEIERSDORF56

HM22/0522

NORRIS, MCLAUGHLIN & MARCUS, PA
ATTORNEYS AT LAW
660 WHITE PLAINS ROAD
TARRYTOWN NY 10591-5144

EXAMINER

LAMM, M

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/367,748	Applicant(s) DIEMBECK ET AL.	
	Examiner Marina Lamm	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

Acknowledgment is made of the amendment filed 4/5/01. Claims pending are 1-16. Claim 17 has been canceled.

Claim Rejections - 35 USC § 112

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of Claims 1, 2, 4-8 and 11-15 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of rosacea and coperoose, does not reasonably provide enablement for the prophylaxis of these conditions, is maintained for the reasons of the record.

As discussed in the previous Office Action, the burden of enabling the prophylaxis or prevention of a disease (i.e. the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to prevent the condition. The instant specification does not provide guidance as to how one skilled in the art would go about screening those patients susceptible to rosacea and couperose. Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compounds in preventing these disease states. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

Claim Rejections - 35 USC § 102

3. The rejection of Claims 1-4, 7-11 and 14-16 under 35 U.S.C. 102(b) as being anticipated by Giacomoni is maintained for the reasons of the record.

As discussed in the previous Office Action, Giacomoni teaches cosmetic compositions containing at least one NO synthase inhibitor in cosmetically acceptable carrier. See Abstract. The compositions of Giacomoni may be used for the treatment of various skin conditions, including rosacea. See p. 8, line 41. The NO synthase inhibitors of Giacomoni include N^G-monomethyl-L-arginine, N^G-nitro-L-arginine and its methyl ester, N^G, N^G-dimethyl-L-arginine and N^G-amino-L-arginine. See p. 4, lines 29-35. Antioxidants such as vitamins E and A may be used in the composition. See p. 7, lines 36-37.

Claim Rejections - 35 USC § 103

4. The rejection of Claims 5, 6, 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Giacomoni in view of either Breton et al. or Ptchelintsev et al. is maintained for the reasons of the record.

As discussed in the previous Office Action, Giacomoni does not teach sunscreens agents of Claims 5, 6, 12 and 13.

However, it is conventional to employ sunscreens agents in cosmetic compositions. See Breton et al. at col. 16, line 53 or Ptchelintsev et al. at col. 6, lines 54-67.

One of ordinary skill would have been motivated to employ sunscreens agents of Breton et al. or Ptchelintsev et al. in compositions of Giacomoni with a reasonable expectation of beneficial results such as sun protecting effect.

Response to Arguments

5. Applicant's arguments filed 4/5/01 have been fully considered but they are not persuasive.

With respect to the rejection of Claims 1, 2, 4-8 and 11-15 under 35 U.S.C. 112, first paragraph, the applicant argues that "ones a physician determines that his patient is in need of treatment for rosacea, or determines that his patient should be treated for the prevention of said disease, the instant specification will enable him to perform such prophylaxis or treatment according to the invention". In response to this argument, it is noted that the instant specification does not provide guidance as to a screening those patients susceptible to rosacea and couperose. Nor is guidance provided as to a specific protocol for proving the efficacy of the presently claimed compounds in preventing these disease states. Therefore, one skilled in the art would not be able to practice the invention as claimed without undue experimentation.

With respect to the rejection of Claims 1-4, 7-11 and 14-16 under 35 U.S.C. 102(b), the applicant argues that the Giacomone reference "neither teaches nor suggests the use of NO synthase inhibitors for the treatment of rosasea". In response to this argument, it is noted that Giacomoni explicitly teaches cosmetic compositions for the treatment of skin conditions, including rosasea, containing at least one NO synthase inhibitor. See Abstract; p. 8, line 41. While reducing the skin irritant effect of certain pharmaceutical substances, the NO synthase inhibitors of Giacomoni will inherently treat rosasea as claimed in the instant claims. In summary, the method taught by the reference is directed to the same purpose and employs the same compounds and method steps as the claimed method. Therefore, the results will be inherently the same.

With respect to the rejection of Claims 5, 6, 12 and 13 under 35 U.S.C. 103 (a), the applicant argues that “nothing in either of these references would suggest combining a sunscreensing agent with a NO-synthase inhibitor”. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill would have been motivated to employ sunscreensing agents of Breton et al. or Ptchelintsev et al. in compositions of Giacomoni for their art-recognized purpose and with a reasonable expectation of beneficial results such as sun protecting effect.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541.

The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ml
5/14/01


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616